(e) *Whom to notify at FDA.* Notifications and reports concerning prescription human drugs and biological products regulated by the Center for Drug Evaluation and Research shall be made to the Division of Compliance Risk Management and Surveillance (HFD–330), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Notifications and reports concerning prescription human biological products regulated by the Center for Biologics Evaluation and Research shall be made to the Division of Inspections and Surveillance (HFM–650), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852.

[64 FR 67756, Dec. 3, 1999, as amended at 69 FR 48775, Aug. 11, 2004; 70 FR 14981, Mar. 24, 2005]

§ 203.38 Sample lot or control numbers; labeling of sample units.

(a) *Lot or control number required on drug sample labeling and sample unit label.* The manufacturer or authorized distributor of record of a drug sample shall include on the label of the sample unit and on the outside container or packaging of the sample unit, if any, an identifying lot or control number that will permit the tracking of the distribution of each drug sample unit.

(b) *Records containing lot or control numbers required for all drug samples distributed.* A manufacturer or authorized distributor of record shall maintain for all samples distributed records of drug sample distribution containing lot or control numbers that are sufficient to permit the tracking of sample units to the point of the licensed practitioner.

(c) *Labels of sample units.* Each sample unit shall bear a label that clearly denotes its status as a drug sample, e.g., ''sample,'' ''not for sale,'' ''professional courtesy package.''

(1) A drug that is labeled as a drug sample is deemed to be a drug sample within the meaning of the act.

(2) A drug product dosage unit that bears an imprint identifying the dosage form as a drug sample is deemed to be a drug sample within the meaning of the act.

(3) Notwithstanding paragraphs (c)(1) and (c)(2) of this section, any article that is a drug sample as defined in section 503(c)(1) of the act and § 203.3(i) that fails to bear the label required in this paragraph (c) is a drug sample.

§ 203.39 Donation of drug samples to charitable institutions.

A charitable institution may receive a drug sample donated by a licensed practitioner or another charitable institution for dispensing to a patient of the charitable institution, or donate a drug sample to another charitable institution for dispensing to its patients, provided that the following requirements are met:

(a) A drug sample donated by a licensed practitioner or donating charitable institution shall be received by a charitable institution in its original, unopened packaging with its labeling intact.

(b) Delivery of a donated drug sample to a recipient charitable institution shall be completed by mail or common carrier, collection by an authorized agent or employee of the recipient charitable institution, or personal delivery by a licensed practitioner or an agent or employee of the donating charitable institution. Donated drug samples shall be placed by the donor in a sealed carton for delivery to or collection by the recipient charitable institution.

(c) A donated drug sample shall not be dispensed to a patient or be distributed to another charitable institution until it has been examined by a licensed practitioner or registered pharmacist at the recipient charitable institution to confirm that the donation record accurately describes the drug sample delivered and that no drug sample is adulterated or misbranded for any reason, including, but not limited to, the following:

(1) The drug sample is out of date;

(2) The labeling has become mutilated, obscured, or detached from the drug sample packaging;

(3) The drug sample shows evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness;